















User's Manual of Spectacles

Spectacles is non-sterile disposable anti-fog Spectacles.

1. Brand: Refine
 2. Product name: Spectacles
 3. Material: PC 100%
 4. Model: EP03
 5. Composition: composed of protective cover and fixing device made of polymer material. Non-sterile, single use.
 6. Applied standards: GB 14866-2006 / EN166:2001 / ANSI/ISEA Z87.1-2015
AS/NZS 1337.3:2010 / CSA Z94.3-2015
 7. Intended use : Spectacles is common eye protection equipment. Recommended industry: Facility Sanitation, Food Processing, Food Safety
 8. Product instruction: The product and the protective packaging should be checked before using. Stop using it if there is any damage.
 9. Precautions:
 - a. One-time use only.
 - b. Use in accordance with the instructions.
 - c. Never use it when damages are found.
 - d. Stay away from chemicals.
 - e. The eye protector is not intended to protect against high speed particles.
 10. Storage: Please store in clean, dry and ventilated indoor place, with relative humidity (10%-93%), Atmospheric pressure for storage (70kPa-106kPa), temperature (-20°C- +40°C), avoid corrosive gas.
-  **Warning:**
- a. Materials which may come into contact with the wearer's skin could cause allergic reactions to susceptible individuals;
 - b. Scratched or damaged oculars should be replaced;
 - c. Eye-protectors against high speed particles worn over standard ophthalmic spectacles may transmit impacts, thus creating a hazard to the wearer.
 - d. These protectors are intended for indoor use where no optical radiation hazards exist.

Symbol instruction

Symbol	Instruction	Symbol	Instruction
	Warning, Caution and Important ! Check the Instruction Manual		EU Representative
	Date of manufacture		Manufacturer
	Recovery		Handle with care
	Keep dry		Consult the accompanying documents
	Atmospheric pressure for storage		Disposable
	Temperature limitation for storage		Lot number
	Humidity limitation for storage		

Symbol	Instruction	Symbol	Instruction
Z87	According to ANSI/ISEA Z87.1-2015	REFINE 1SN EN166 S	According to EN 166:2001, REFINE - manufacture LOGO 1 - Optical class (Class I) S - Symbol for increased robustness N - Symbol for Resistance to fogging of oculars EN 166 - Product Standards S - Symbol for Increased robustness
EAC	EAC certification		
CE	CE certification		



Guilin Refine Medical Instrument Co., Ltd.

No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R. China



MedPath GmbH

Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Shelf life: 2 Years

Applied standards: GB 14866-2006 / EN166:2001 / ANSI/ISEA Z87.1-2015

AS/NZS 1337.3:2010 / CSA Z94.3-2015



EU DECLARATION OF CONFORMITY

1. PPE (product, type, batch or serial number):

Spectacles, EP03, Category II, AZ631

2. Name and address of the manufacturer and, where applicable, his authorized representative:

Manufacturer: Guilin Refine Medical Instrument Co.,LTD.

Address of the manufacturer: No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R.China

Authorised representative: MedPath GmbH

Address of the Authorised representative: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer: Guilin Refine Medical Instrument Co.,LTD.

No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, P.R.China

4. Object of the declaration (Identification of PPE allowing traceability; where necessary for the identification of the PPE a colour image of sufficient clarity may be included):



EP03:

Traceability Labeling:

Spectacles

Brand: Refine

Model: EP03

Lot No.: **AZ631**

Production Date: June 2020

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation: Regulation (EU) 2016/425

6. References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications; including the date of the specification, in relation to which conformity is declared:

Harmonised Performance Standard No(s): **EN 166:2001**

Technical specification No(s): **RF-EP3-T001**

Test Reports: **C80272046R001**

7. Where applicable, the notified body UL International (Netherlands) B.V. (European Notified Body No. 2821) performed the EU type-examination Module B and issued the EU type-examination certificate : **2821-PPE-0003.**

Signed for and on behalf of Guilin Refine Medical Instrument Co.,LTD.

(place and date of issue): **Guilin , 2020-06-07**

Name: Jordan Chen, Title: Management representative (signature):

Jordan Chen

